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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/725,475 | 12/03/2003 | Mark Zoller | 54074D8 | 4496 |

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| EXAMINER |
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LANDSMAN, ROBERT S

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| ART UNIT | PAPER NUMBER |
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1647

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 01/24/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/725,475 | Applicant(s) ZOLLER ET AL. | |
| | Examiner Robert Landsman | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 194-206 and 209-309 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 194-206 and 209-309 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment filed 12/19/06 has been entered into the record.
- B. Claims 194-256 were pending. Claims 207 and 208 have been canceled and new claims 257-309 have been added. Therefore, claims 194-206 and 209-309 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Oath

- A. The objection to the Oath has been withdrawn in view of Applicants' arguments.

3. Specification

- A. All objections to the specification have been withdrawn in view of Applicants' amendments except for the following – Though Applicants have pointed out that Figure 3C does appear in the Brief Description, the beginning of the Description must refer to Figure 3C (e.g. "Figures 3A-3C contain...")
- B. Figure 1 is objected to since it recites "rate" instead of "rat."
- C. Figure 1 is further objected to since the names of all the T1Rs are not legible. This is especially important since various claims refer to this Figure.

4. Election by Original Presentation

- A. Newly submitted claims 258 and 260-271 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are drawn to "cells" whereas the original claims are drawn to methods.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. However, claim 258 and 260-271 **WILL NOT BE WITHDRAWN FROM CONSIDERATION** as being directed to a non-elected invention since it is believed these claims were added in error and should

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likely be drawn to “A method of claim ____ wherein a cell...” See 37 CFR 1.142(b) and MPEP § 821.03. The Examiner will wait for Applicants’ response before taking further action.

It is noted that reciting “wherein the cell” has no antecedent basis.

5. Claim Objections

A. All claim objections have been withdrawn in view of Applicants’ amendments to, or cancellation of, the claims.

B. Claim 232 remains objected to and new claim 285 is also objected to. It is believed that the claims should recite “effect of said compound” instead of “on.”

C. Claims 257-309 are objected to since, in claim 257, the term “receptor associated” should be hyphenated.

D. Claim 295 is objected to since they are incomplete.

E. Claim 305 is objected to since “ligand specific” should be hyphenated.

6. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 194-206 and 209-256 remain rejected and new claims 257-309 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 9/20/06. Applicants have amended the claims to further limit the claimed genus. However, the genus of T1R2 and T1R3 receptors is still excessive with regard to claims 194, 206 and 218. These claims encompass the genus of receptors which hybridize under specific conditions to known receptors. Applicants imply in their claims that T1R2 and T1R3 receptors from 3 different species have been disclosed. However, due to the poor reproduction quality of Figure 1, which discloses the supposed receptors, the Examiner cannot identify three T1R2 and T1R3 receptors. Therefore, it appears Applicants have only provided guidance and working examples of, at most, two **T1R2 receptors and two T1R3 (rat and human) receptors** and nucleic acids (Figure 1). Therefore, undue experimentation would be required for the artisan to make and use the invention as claimed.

In addition, claim 258 recites that the receptors are “**derived from**” the same species. Again, the breadth of the claims is excessive with regard to claiming all T1R2/T1R3 receptors which are “derived

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from” a particular animal species. Applicants have only identified one T1R2 sequence and two T1R3 sequences. Derivatives would have one or more amino acid substitutions, deletions, insertions and/or additions to the claimed proteins.

The Examiner may withdraw this rejection with regard to the genus of T1R2 and T1R3 receptors if Applicants can demonstrate that these genii were well known at the time of the present invention (i.e. more than two known receptors) and that the structural similarities were sufficient enough for the artisan to identify members of these genii.

B. The rejection of claims 194-256 under 35 USC 112, first paragraph, regarding being able to identify “activators” of the receptor complex has been withdrawn in view of Applicants’ amendments to the claims to remove this language. The claims have been amended to recite “modulates the activity” which, due to the number of activities claimed, such as second messenger activity, is enabled.

C. Claim 306 is rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide any guidance or working examples as to which hormones and transmitters are modulated by the T1R2/T1R3 receptor complex. Therefore, it is not predictable to the artisan as to which hormones and/or transmitters to measure. Furthermore, it is unclear if the scope of the claims is intended to be limited to neurotransmitters. If not, it is not clear as to what other types of “transmitters” the claims encompass.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 194-206 and 209-256 remain rejected and new claims 257-309 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on page 5 of the Office Action mailed 9/20/06. Applicants have amended the claims to further limit the claimed genus. These claims encompass the genus of receptors which hybridize under specific conditions to known receptors. However, the genus of T1R1 and T1R3 receptors is still not described.

Applicants recite, or imply, in their claims that T1R2 and T1R3 receptors from 3 different species have been disclosed. However, due to the poor reproduction quality of Figure 1, which discloses the supposed receptors, the Examiner cannot identify three T1R2 and T1R3 receptors. Therefore, it appears

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Applicants have only adequately described at most two **T1R2** and two **T1R3 (rat and human) receptors** and nucleic acids and not the genus of each.

In addition, claim 258 recites that the receptors are “**derived from**” the same species. Again, genus of all T1R2/T1R3 receptors which are “derived from” a particular animal species is not well described. Applicants have only identified at most two T1R2 sequence and two T1R3 sequences. Derivatives would have one or more amino acid substitutions, deletions, insertions and/or additions to the claimed proteins.

The Examiner may withdraw this rejection with regard to the genus of T1R2 and T1R3 receptors if Applicants can demonstrate that these genii were well known at the time of the present invention (i.e. more than two known receptors) and that the structural similarities were sufficient enough for the artisan to identify members of these genii.

8. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 194-206 and 209-309 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have added hybridization conditions into at least claims 194, 206 and 218 and state that support for these conditions can be found throughout the specification. However, upon reviewing the large specification, the Examiner was unable to find any disclosure of the exact conditions newly added to the claims.

9. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendments to, or cancellation of, the claims.

B. Claims 258 and 260-271 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite “the cell” in the preamble. However, the originally elected claims are drawn to methods. There is insufficient antecedent basis for this limitation in these claims. It is believed that these claims should recite “the method of claim ____ wherein the cell...”

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C. Claims 257-309 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 257 recites "receptor-associated taste." However, this term is unclear. It is not understood how the receptor and taste are associated.

10. Double Patenting

A. Claims 194-206 and 209-256 remain rejected and new claims 257-309 are also rejected for the reasons already of record on pages 7-8 of the Office Action 9/27/06. Applicants ask that this rejection be held in abeyance until the application is allowable.

11. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER